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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,788	01/10/2001	Keith Anderson	6116.200-US	8259

7590 12/30/2005

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,788	ANDERSON ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,15,16,18,19,21-23 and 25-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,15,16,18,19,21-23 and 25-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendments, received 9/29/05, in which applicant amended claims 1, 15, 16, 18, 19, 21, 22, 23, 25, and 26; cancelled claims 14, 17, 20, and 24; and added new claim 27.

Claims 1-3, 5-8, 15-16, 18-19, 21-23, and 25-27 are pending.

Double Patenting

Claims 1 and 27 stand/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No.6,268,343 and claims 11-15 of U.S. Patent No. 5,767,068 for the reasons of record which are restated below.

Claims 1 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No.6,268,343. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um.

.Claim 1 of the '343 patent is a GLP-1 derivative having a lipophilic substituent at Lys-26, optionally via a spacer. Claims 11-15 of the '068 patent teaches nebulizing a peptide in a range of 1-5 um in order to be therapeutically effective.

Claims 1 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 48 and 49 of copending Application No.09/772,607 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant invention is drawn to a formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um . Claim 48 of the '607 application is a derivative of GLP-1 or an analog thereof wherein a lipophilic substituent having 8 to 40 carbon atoms and optionally having an amino group is optionally via a spacer attached to the C-terminal amino acid of GLP-1 . Claim 49 of the '607 application is a derivative of claim 48, wherein the lipophilic substituent has 12 to 35 carbon atoms. Claims 11-15 of the '068 patent teaches nebulizing a peptide in a range of 1-5 um in order to be therapeutically effective.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the rejection is rendered moot by the amendments to the claims presented herein which incorporate the limitations of non-rejected (and now cancelled) claims 14 and 17 into claim 1 and which add a new claim 27 that incorporates the limitations of non-

rejected (and now cancelled) claims 20 and 24. However, the examiner contends that the '343 patent discloses the same formulation containing the same GLP-1 compound as the instant application and column 168, lines 1-3, column 169, lines 34-36 and claims 28-30 of the '343 patent disclose the use of a liquid formulation comprising the GLP-1 compound that can be used for nasal administration, Claims 11-15 of the '068 patent teaches nebulizing a peptide in a range of 1-5 um in order to be therapeutically effective.

The '607 application discloses a pharmaceutical composition comprising the derivative of GLP-1 or an analog thereof and a carrier, which can be used for nasal administration, see, i.e., for example, page 7, lines 5-37. Claims 11-15 of the '068 patent teaches nebulizing a peptide in a range of 1-5 um in order to be therapeutically effective.

Claim Rejections - 35 USC § 103

Claims 1-3, 5-8, 15-16, 18-19, 21-23, and 25-27 stand/ are rejected under 35 U.S.C. 103(a) for the reasons of record which are restated below.

Claims 1-3, 5-8, 15-16, 18-19, 21-23, and 25-27 are rejected under 35 U.S.C. 103(a) as being obvious over Kundsen et al. (USPN 6,268,343) in view of VanDevanter et al. (USPN 5,767,068).

The applied reference is believed to have a common assignee with the instant application because no assignee data is available. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C.

103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant invention is drawn to a liquid formulation comprising a GLP-1 compound having attached thereto a lipophilic substituent comprising 14-18 carbon atoms, where said attachment of said lipophilic subsituent to said GLP-1 compounds is optionally via a spacer and wherein said formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um.

Knudsen et al teaches a GLP-1 derivative having a lipophilic substituent at Lys-26, optionally via a spacer, see, i.e., for example, abstract and claim 1. Knudsen does not teach formulation upon nebulization achieves a mass median aerodynamic diameter of less than 10 um.

VanDevanter teaches nebulizing a peptide in a range of 1-5 um in order to be therapeutically effective, see i.e., for example, column 3, lines 3-30 and claims 11-15.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Knudsen with the beneficial teachings of VanDevanter, because Knudsen discloses the use of a liquid formulation comprising the GLP-1 compound that can be used for nasal administration

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the rejection is rendered moot by evidence of common ownership of the present application and USPN 6,268,343. However, the examiner contends that the '343 patent discloses the same formulation containing the same GLP-1 compound as the instant application and column 168, lines 1-3, column 169, lines 34-36 and claims 28-30 of the '343 patent disclose the use of a liquid formulation comprising the GLP-1 compound that can be used for nasal administration, thus it would be obvious that the formulation would achieve a mass medium aerodynamic diameter of less than 10 um upon nebulization, when used in conjunction with the '068 patent.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Bruce Campell

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